GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2476
ANSWERED ON:15.12.2004
PERMISSION FOR IMPORTING DRUGS
Singh Shri Sitaram

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether permission of the Union Government is likely to be made compulsory for importing medicines to conduct trials on human beings by researchers;

(b) if so, the details thereof; and

(c) the time by which it is likely to be implemented?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (c): Under Rule 33 of Drugs and Cosmetics Rules relating to Import of drug for examination, test or analysis, small quantities of drugs, the import of which is otherwise prohibited under Section 10 of the Act, may be imported for the purpose of examination, test or analysis. The aplicant is required to make an application in Form-12 alongwith prescribed fee for import of small quantities of drugs/medicines for clinical trial purpose. Drugs can be imported for such purpose only after licence for the same is issued in form 11 under the Drugs and Cosmetics Rules.